Application No. 09/782,184 Amendment Dated July 22, 2003 Reply to Office Action of January 22, 2003

REMARKS/ARGUMENTS

This is in response to the Office Action dated January 22, 2003. Independent claims 1, 18 and 19 are amended herein. Claims 1-36 are currently pending.

Rejection Under 35 U.S.C. 112

The Examiner rejected claims 1-36 under 35 USC 112, first paragraph. Independent claims 1, 18 and 19 are amended herein to remove the phrase on which the Examiner based the rejection of these claims. Reconsideration of these claims as amended is respectfully requested.

Double Patenting:

Applicant herein submits a terminal disclaimer with respect to U.S. Patent No. 6,509,027 to obviate the double patenting rejection raised by the Examiner. Allowance of these claims is respectfully requested.

Rejection Under 35 U.S.C. 103(a):

Claims 1-8 and 12-17 are rejected under 35 U.S.C. 103(a) based on Haynes (U.S. 4725442) by itself or in view of Burke (U.S. 5552156).

Claims 9-11 and 18-36 are also rejected under 35 U.S.C. 103(a) based on Haynes or in combination with Burke, and further in view of WO 99/16001.

As described in amended independent claim 1, the claimed invention is directed to an injectable pharmaceutical composition comprising an aqueous suspension of microdroplets suitable for intravenous delivery. The microdroplets include a substantially water-insoluble, pharmacologically acceptable lipophilic liquid vehicle having at least one membrane-forming lipid and a camptothecin dissolved in the lipophilic liquid vehicle, and also an outer layer formed of a phospholipid. None of the references as described by the Examiner in the Office Action suggests or discloses these and other limitations as recited in claim 1.

Attorney Docket No.: 12636-898

Application No. 09/782,184 Amendment Dated July 22, 2003 Reply to Office Action of January 22, 2003

In particular, the Examiner cites Haynes with respect to prior claim 1 as disclosing "microdroplets (200 angstroms up to a micron) of water insoluble drugs containing a pharmaceutically acceptable liquid surrounded by a layer of phospholipid, which are suitable for injection (Note the abstract, columns 2-8, and claims)." [p.4.] The Examiner similarly contends with respect to prior claims 18 and 19 that Haynes "discloses microdroplets (200 angstroms up to a micron) of water insoluble drugs containing pharmaceutically acceptable liquid surrounded by a layer of phospholipid (Note the abstract, columns 2-8, and claims)." [p.5.] The cited references as explained by the Examiner do not disclose or suggest the invention as described by each and every limitation in these claims.

Accordingly, Applicants respectfully request reconsideration and allowance of independent claims 1, 18 and 19, and also the claims dependent thereon.

Attorney Docket No.: 12636-898

Application No. 09/782,184 Amendment Dated July 22, 2003 Reply to Office Action of January 22, 2003

CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested. Should the Examiner have any questions, please contact the undersigned attorney.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 12636-898).

Respectfully submitted,

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Date: 7/22/03

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